EXHIBIT B

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Barbara Heidel, et al. v. Ethicon, Inc.., et al No. 2:12-cv-00878	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Marc J. Bern and Partners Law Firm to give medical opinions related to Barbara Heidel. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including autologous tissue based slings, biological graft-based

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slings, and periurethral bulking procedures. I have attended training provided by Ethicon, Inc. including training on TVT devices. Additionally, I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT-O device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Barbara Heidel:

- Methodist Medical Center
- Deposition, Barbara Heidel

In addition I have reviewed the following medical literature, relevant depositions and other TVM related documents (provided separately as my reliance list) to assist in formulating my opinions.

Clinical History

- On July 1st, 2005, Mrs. Heidel underwent a posterior repair and TVT-O sling placement by Dr. Brad Carter. Her admission history and physical memorialized that she was a "55 year old gravida 2 para 2 who has developed problems with stress urinary incontinence (SUI) and has also been noted to have a small but symptomatic rectocele."

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Her past medical history was in part remarkable for a cold knife conization in 1986, bilateral tubal ligation, bunion surgeries, sinus surgery, arthritis, peptic ulcer disease, and [redacted] Review of systems was positive for constipation and hemorrhoids as well as SUI. Her surgery proceeded uneventfully. The sling was set in a tension-free fashion such that there was no "impingement on the sling".

Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes in order to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT-O, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk-benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

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It is my opinion the IFU for the TVT-O in 2005 was not sufficient to enable informed consent from the patient. The TVT-O IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction (i.e. too much tension) applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina,

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peri-vaginal, and those tissues adjacent to the mesh persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT-O IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. It is my opinion that a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2005 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.

In 2005, alternative successful and safer sling procedures were available, including biologic slings and autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Heidel was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT-O IFU inherent to the risks of using synthetic mesh as an alternative to autologous fascia. As such, Dr. Carter was unable to warn Mrs. Heidel of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Heidel suffered vaginal sling contraction as a result of the physical properties of the TVT device. When vaginal slings contract they cause obstructive voiding symptoms. These symptoms are documented in Mrs. Heidel's deposition which describe urinary symptoms of hesitancy, slow stream, and incomplete bladder emptying (Heidel deposition, pages 39-40)

A. Contraction

Mrs. Heidel's TVT contracted post implantation. Despite being initially placed in a tension free fashion consistent with the IFU, the TVT contracted. This is evidenced by Mrs. Heidel's development of urinary hesitancy, incomplete bladder

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emptying symptoms and slow stream following an otherwise uncomplicated sling insertion procedure by Dr. Carter.

I have observed bladder outlet obstruction in my clinical practice that is the result of post-implantation contraction or shrinkage of the mesh. I have also observed mesh retraction following incision of mesh in revision and excision procedures, consistent with mesh contraction.

Case Specific Opinion No. 2

Mrs. Heidel's vaginal pain and dyspareunia was caused by contraction of the TVT device and possible scar plate formation. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury; (7) lichen sclerosis; (8) vaginal tissue atrophy; and (8) pelvic floor dysfunction. [1]

I am able to rule in contraction and scarring as potential causes of Ms. Heidel's vaginal pain and dyspareunia. Her obstructive voiding symptoms are memorialized in the deposition testimony of Mrs. Heidel. These symptoms are a direct result of mesh contraction. Although scarring is not a readily identifiable finding in the medical records reviewed, the description of Mrs. Heidel's spouse hitting "a wall" (page 32 of her deposition) suggests either scarring or her sling being sources of her dyspareunia. In addition her persistent left groin pain is along the expected course of the left arm of the TVT-O sling and is likely an area of dense fibrosis and scar.

Her posterior repair should be mentioned in the differential as there can be scarring related to this repair that may also result in dyspareunia. Mrs. Heidel's description of the location of her dyspareunia pain, however, is not consistent with her dyspareunia being related to this as she describes the pain as being "up high" and in the "middle" of her vagina (page 34 of her deposition). Dyspareunia as a complication of her posterior repair would be low (i.e. along the posterior wall of the vagina).

[1] (Ashok, 2012)

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Neuromuscular injury is excludable as the cause of Mrs. Heidel's dyspareunia. Mrs. Heidel never suffered from any diagnosed neurological conditions that would otherwise result in dyspareunia

Vaginal tissue atrophy is excludable as the cause of Mrs. Heidel's dyspareunia. Although she diagnosed with atrophic vaginitis and successfully treated for this condition with Premarin cream, it had no impact on her dyspareunia

I am able to exclude pelvic floor dysfunction, paraurethral banding, and lichen sclerosis as causes of Mrs. Heidel's dyspareunia as she has never been diagnosed with these conditions.

Case Specific Opinion No. 3

Mrs. Heidel's future prognosis as it relates to her pelvic pain, dyspareunia, and voiding dysfunction is guarded. Because she has residual pelvic mesh and resultant scarring she will continue to suffer from pelvic pain and dyspareunia. Moreover, she has chronic, persistent left groin pain in the area of the left arm of her TVT-O sling. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. I anticipate that if further surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure.

In as much as physical therapy might be somewhat helpful at improving her pelvic pain and dyspareunia, they most certainly will not completely resolve the symptoms she currently suffers from. In summary, within a reasonable degree of medical certainty, the voiding dysfunction, pelvic pain, and dyspareunia will be a lifelong condition for this patient. Moreover, alternative successful and safer sling procedures were available at the time of her original synthetic mesh sling implantation, including the use of a biologic graft or an autologous fascial graft with suture. These safer alternative sling procedures would not have resulted in the same symptoms and injuries that Mrs. Heidel now suffers.

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These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion.

Sincerely,

Konstantin Walmsley, M.D.

1/17/17